



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

November 25, 2014

Paragonix Technologies, Inc.  
% Mason Diamond  
Regulatory Consultant  
Texel Fortis, LLC  
150 Levinberg Lane  
Wayne, NJ 07470

Re: K143054  
Trade/Device Name: Sherpa Pak Kidney Transport System  
Regulation Number: 21 CFR 876.5880  
Regulation Name: Isolated Kidney Perfusion And Transport System And Accessories  
Regulatory Class: Class II  
Product Code: KDN, PIN  
Dated: November 7, 2014  
Received: November 10, 2014

Dear Mason Diamond,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Benjamin R. Fisher -A**

Benjamin Fisher  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Submitter:  
**Paragonix Technologies, Inc.**

**Paragonix Sherpa Pak Kidney Transport System**  
Premarket Notification: Special 510(k)

## **Section 7.0**

### **Indications for Use Statement**

Submitter:  
Paragonix Technologies, Inc.

Paragonix Sherpa Pak Kidney Transport System  
Premarket Notification: Special 510(k)

## Indications for Use

510(k) Number (if known):   K143054  

Device Name: **Paragonix Sherpa Pak Kidney Transport System**

Indications For Use:

**“The Sherpa Pak Kidney Transport System is intended to be used for the static hypothermic preservation of kidney organs during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with these organs.**

**The Sherpa Pak Kidney Transport System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.”**

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Premarket Notification: Special 510(k)

**Section 8**  
**510(k) Summary**

Submitter: **Paragonix Sherpa Pak Kidney Transport System**  
**Paragonix Technologies, Inc.** Premarket Notification: Special 510(k)

**510(k) Summary**

**Paragonix Sherpa Pak Transport System Kit**

**K143054**

**Submitter:** Paragonix Technologies, Inc.  
c/o Vaughn & Associates  
639 Granite Street  
Braintree, MA 02184

**Contact Person:** Mason W. Diamond, DDS  
Texel Fortis, LLC  
150 Levinberg Lane  
Wayne, NJ 07470  
Phone: 508-333-0108  
Fax: 973-305-0213  
masonwd@aol.com

**Date Prepared:** November 7, 2014

**Trade Name:** Paragonix Sherpa Pak Kidney Transport System

**Classification Name:** Isolated kidney perfusion  
and transport system and accessories

**Regulation Number:** 21 CFR 876.5880

**Product Codes:** Classification - KDN  
Subsequent - PIN

**Predicate Devices:** Sherpa Pak Kidney Transport System (Paragonix Technologies, Inc) - K133694  
Belzer UW Cold Storage Solution (DuPont Merk Pharmaceutical Company) - K944866  
CoStorSol (Preservation Solutions Inc) – K091245  
SPS-1 (Organ Recovery Systems, Inc) – K091656  
Custodiol HTK Solution (Dr Franz Köhler Chemie GmbH) – K043461

**Device Description:** The Paragonix Sherpa Pak Kidney Transport System is a device intended to provide a safe, consistent method for cold ischemic storage and transport of donor organs to recipients for transplantation. The Sherpa Pak System consists of 1) an outer shipper which contains various non-ice based temperature controlled packaging elements, 2) an inner and outer hard shell container (i.e. Sherpa Pak/Sherpa Pak Shell) which provides a double, rigid barrier container in which the kidney is immersed and suspended in a Cold Storage Fluid cleared for use in storing and transporting donor organs and 3) a temperature display and timer to monitor temperature

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and elapsed time of transport, respectively. The device is identical to the cleared Sherpa Pak Kidney Transport System in all respects.

The purpose for this change is to allow the Paragonix Sherpa Pak Kidney Transport System to be distributed with any FDA-cleared, commercially-available preservation solution, as a Convenience Kit.

**Intended Use:** Organ storage and preservation for transplantation.

**Indications for Use:** The Sherpa Pak Kidney Transport System is intended to be used for the static hypothermic preservation of kidney organs during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with these organs.

The Sherpa Pak Kidney Transport System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.

**Functional Testing:** Descriptive information and laboratory bench testing were provided to demonstrate the device meets its design specifications, performs as intended, and is safe for its intended use. Additional biocompatibility testing was not necessary as there were no material changes from the device cleared under K133694.

Specifically, testing to demonstrate that the Sherpa Pak Kidney Transport System provided a transport system robust enough to protect the donor organ during transport and maintained temperature throughout the duration of transport was included. Thermal qualification demonstrated the ability of the Sherpa Pak Kidney Transport System to maintain the required temperature through 24 hours.

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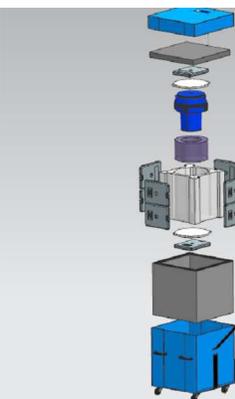
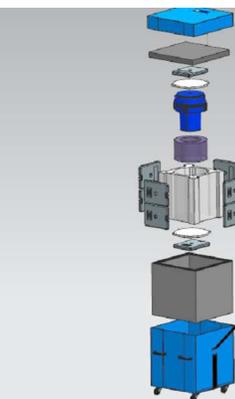
**Device Characteristic Comparison**

Characteristic	Proposed Sherpa Pak Kidney Transport System K143054	Sherpa Pak Kidney Transport System - K133694	Belzer UW Cold Storage Solution - K944866	CoStorS ol Cold Storage Solution - K091245	SPS-1 – K091656	Custodiol HTK Solution – K043461
<b>Intended Use</b>	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.
<b>Indications for Use</b>	<p>“The Sherpa Pak Kidney Transport is intended to be used for the static hypothermic preservation of kidney organs during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with these organs.</p> <p>The Sherpa Pak Kidney Transport can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.”</p>	<p>“The Sherpa Pak Kidney Transport is intended to be used for the static hypothermic preservation of kidney organs during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with these organs.</p> <p>The Sherpa Pak Kidney Transport can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.”</p>	<p>“Belzer UW Cold Storage Solution is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.”</p>	<p>“CoStorSol® is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.”</p>	<p>“SPS-1 is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.”</p>	<p>“Custodiol HTK Solution is indicated for perfusion and flushing donor kidneys, liver, pancreas and heart prior to removal from the donor or immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and eventual transplantation (not for continuous perfusion) to the recipient.”</p>
<b>Regulation Number</b>	878.5880	878.5880	878.5880	878.5880	878.5880	878.5880
<b>Product Code</b>	KDN and PIN	KDN	KDL	KDN	KDN	KDL and MSB
<b>Device Classification Name</b>	Device Classification Name – Isolated kidney perfusion and transport system and accessories	Device Classification Name – Isolated kidney perfusion and transport system and accessories	Device Classification Name – Set, perfusion, kidney, disposable	Device Classification Name – Isolated kidney perfusion and transport system and accessories	Device Classification Name – Isolated kidney perfusion and transport system and accessories	Device Classification Name – Isolated kidney perfusion and transport system and accessories
<b>Mode of Operation</b>	Static cold ischemic storage	Static cold ischemic storage	Static cold ischemic storage	Static cold ischemic storage	Static cold ischemic storage	Static cold ischemic storage
<b>Meets UNOS Policy 5<sup>1</sup></b>	Yes	Yes	Yes	Yes	Yes	Yes

<sup>1</sup> <http://www.optn.transplant.hrsa.gov>

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Characteristic	Proposed Sherpa Pak Kidney Transport System K143054	Sherpa Pak Kidney Transport System - K133694	Belzer UW Cold Storage Solution - K944866	CoStorS ol Cold Storage Solution - K091245	SPS-1 – K091656	Custodiol HTK Solution – K043461
<b>Organ container</b>	Two rigid airtight containers one of which contains the cold storage solution in which the organ is immersed.	Two rigid airtight containers one of which contains the cold storage solution in which the organ is immersed.	None. Solution is used by organ procurement centers but requires an organ container such as that used in the proposed Sherpa Pak Transporter System or the Avid custom procedure tray tub.	None. Solution is used by organ procurement centers but requires an organ container such as that used in the proposed Sherpa Pak Transporter System or the Avid custom procedure tray tub.	None. Solution is used by organ procurement centers but requires an organ container such as that used in the proposed Sherpa Pak Transporter System or the Avid custom procedure tray tub.	None. Solution is used by organ procurement centers but requires an organ container such as that used in the proposed Sherpa Pak Transporter System or the Avid custom procedure tray tub.
<b>Cooling</b>	Temperature preconditioned storage solution and temperature controlled packaging including preconditioned phase change material cold packs, PIR insulating panels, and Expandable Polystyrene panels	Temperature preconditioned storage solution and temperature controlled packaging including preconditioned phase change material cold packs, PIR insulating panels, and Expandable Polystyrene panels	Temperature preconditioned. Relies on transport system for type of cooling and maintenance of temperature	Temperature preconditioned. Relies on transport system for type of cooling and maintenance of temperature.	Temperature preconditioned. Relies on transport system for type of cooling and maintenance of temperature.	Temperature preconditioned. Relies on transport system for type of cooling and maintenance of temperature.
<b>System components</b>	 <ul style="list-style-type: none"> <li>• Outer plastic corrugated container (top and base with wheels)</li> <li>• PIR insulating panels</li> </ul>	 <ul style="list-style-type: none"> <li>• Outer plastic corrugated container (top and base with wheels)</li> <li>• PIR insulating panels</li> </ul>	Plastic bag with cold storage solution to be used in combination with some type of organ transport container (e.g., such as the Avid custom procedure kit and off-the-shelf cooler).	Plastic bag with cold storage solution to be used in combination with some type of organ transport container (e.g., such as the Avid custom procedure kit and off-the-shelf cooler).	Plastic bag with cold storage solution to be used in combination with some type of organ transport container (e.g., such as the Avid custom procedure kit and off-the-shelf cooler).	Plastic bag with cold storage solution to be used in combination with some type of organ transport container (e.g., such as the Avid custom procedure kit and off-the-shelf cooler).

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Characteristic	Proposed Sherpa Pak Kidney Transport System K143054	Sherpa Pak Kidney Transport System - K133694	Belzer UW Cold Storage Solution - K944866	CoStorS ol Cold Storage Solution - K091245	SPS-1 – K091656	Custodiol HTK Solution – K043461
	<ul style="list-style-type: none"> <li>• PCM Cold Pack Panels</li> <li>• EPS panels</li> <li>• Sherpa Pak and Sherpa Pak Shell without connector</li> <li>• Temperature data logger</li> <li>• Timer</li> <li>• Plastic bags with cold storage solution to be used in combination with the Sherpa Pak Kidney Transporter System [supplied in a separate package].</li> </ul>	<ul style="list-style-type: none"> <li>• PCM Cold Pack Panels</li> <li>• EPS panels</li> <li>• Sherpa Pak and Sherpa Pak Shell without connector</li> <li>• Temperature data logger</li> <li>• Timer</li> </ul>				
<b>Single Use/Reuse</b>	Entire system is single use/patient only.	Entire system is single use/patient only.	Single use/patient only.	Single use/patient only.	Single use/patient only.	Single use/patient only.
<b>Sterilization</b>	Sherpa Pak and Sherpa Pak Shell are sterilized by gamma irradiation. All other components are non-sterile.	Sherpa Pak and Sherpa Pak Shell are sterilized by gamma irradiation. All other components are non-sterile.	Sterilized.	Sterilized.	Sterilized.	Sterilized.

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Characteristic	Proposed Sherpa Pak Kidney Transport System K143054	Sherpa Pak Kidney Transport System - K133694	Belzer UW Cold Storage Solution - K944866	CoStorS ol Cold Storage Solution - K091245	SPS-1 – K091656	Custodiol HTK Solution – K043461
<b>Biocompatibility</b>	Direct and indirect organ contact materials have been tested for biocompatibility.	Direct and indirect organ contact materials have been tested for biocompatibility.	Yes.	Yes.	Yes.	Yes.
<b>Intended storage time</b>	Device can maintain 4° C to 8° C through 24 hours	Device can maintain 4° C to 8° C through 24 hours	No time within indication statement	No time within indication statement	No time within indication statement	No time within indication statement

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**Summary of Design  
Changes:**

The design, indications for use, principles of operation, technological characteristics, and packaging of the Sherpa Pak Kidney Transport System are exactly the same as the previously cleared Sherpa Pak Kidney Transport System (K133694). Sherpa Pak Kidney Transport System is intended to be used with any preservation solution that is cleared by the FDA for use with kidneys, and, therefore, the combined kitting of the Paragonix Sherpa Pak Kidney Transport System and any FDA-Cleared preservation solution (i.e., Belzer UW, CoStorSol, SPS-1, Custodiol HTK, etc.) falls within the current scope of use for the aforementioned devices. The purpose for this change is to allow the Paragonix Sherpa Pak Kidney Transport System to be distributed with any FDA-cleared, commercially-available preservation solution, as a Convenience Kit. According to the FDA "Convenience Kits Interim Regulatory Guidance" (May 20, 1997), the Sherpa Pak Kidney Transport System falls within the definition of a Convenience Kit under the generic heading of a "Kidney Perfusion Kit." As a result, no further testing is required.